



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-972/S-026

Wyeth Pharmaceuticals, Inc.
Attention: Ms. Patricia Kuker Staub
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Kuker Staub:

Please refer to your supplemental new drug application dated April 10, 2003, received April 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordarone (amiodarone HCl) 200 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling revised to read as follows:

1. Under **INDICATION AND USAGE**, "... (see **"WARNINGS"** below) ..." has been changed to "... see **"WARNINGS"** below ..." (quotation marks unbolded, and a space added).
2. Under **ADVERSE REACTIONS/Postmarketing Reports**, "syndrome of inappropriate antidiuretic hormone secretion (SIADH)" has been added.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 10, 2003.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Russell Fortney
Regulatory Health Project Manager
301-594-5311

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Doug Throckmorton
5/6/03 08:09:19 AM